

1. 510(k) SUMMARY

DEC 30 2010

September 13st, 2010

K103122

Office of Device Evaluation
U.S. Food & Drug Administration

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food & Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby made of the intention of AAT Alber Antriebstechnik GmbH to introduce into interstate commerce for commercial distribution the motorized lift devices c-max and s-max.

The following information is being submitted in conformance with CDRH-Guidance document "Bundling Multiple Devices in a Single Application", 21 CFR Part 807.87, the "DCRND Guidance for Format and Content for Premarket Notification (510(k)) Submissions", the DCRND November 1996 Draft "Reviewer Guidance for Premarket Notification Submissions: Anesthesiology and Respiratory Devices Branch" Guideline as follows.

1.1 Applicant: AAT Alber Antriebstechnik GmbH
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Organization Number: 239600

1.2 Contact Person: Mrs. Stefanie D. Bankston
BEO MedConsulting Berlin GmbH
2611 Shark Circle
Texas City TX 77591
Phone: (409) 229 0022
email: s.bankston@beoberlin.de

1.3 Devices Name:

- a. Proprietary: c-max, c-max U1, c-max U1 160kg, c-max U2, c-max U2 160kg
s-max, s-max aviation, s-max sella, s-max sella 160kg, s-max sella aviation
- b. Common Name: Wheelchair elevator
- c. Classification Name: Wheelchair elevator
- d. Device Class: II, 21 CFR 890.3930
- e. Classification Panel: Physical Medicine
- f. Product Code: ING

1.4 Performance Standards:

The devices meet the performance standards:

EN 12182: 1999 Technical aids for disabled persons-general requirements and test methods
ISO 7176-14:2008 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters -Requirements and test methods
ISO 7176-16:1997 Wheelchairs - Part 16: Resistance to ignition of upholstered parts -- Requirements and test methods

ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
 ISO 7176-23: 2002 Wheelchairs - Part 23: Requirements and test methods for attendant-operated stair-climbing devices

1.5 Intended Use:

The products c-max and s-max offer motorized stair-climbing support for disabled seated persons to move from one level to another with or without manual wheelchair adaption.

1.6 Device Description:

s-max family

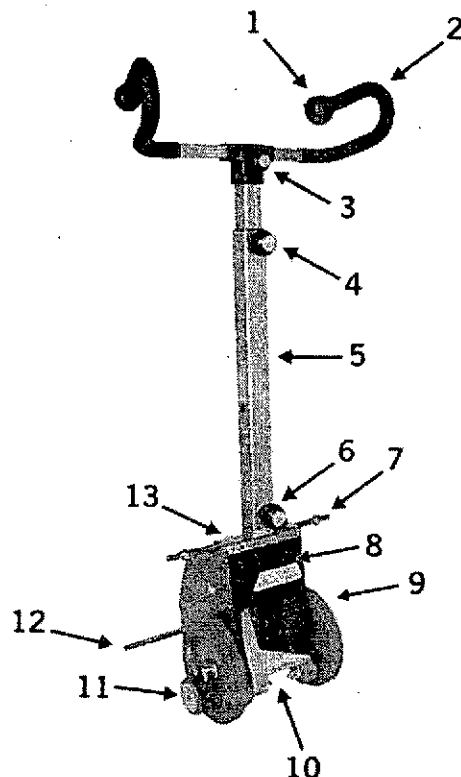
2.2 Features of the s-max

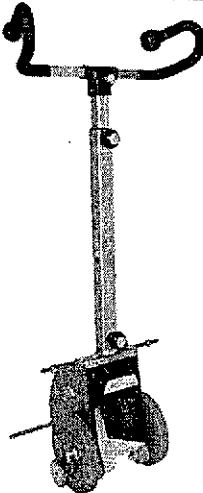
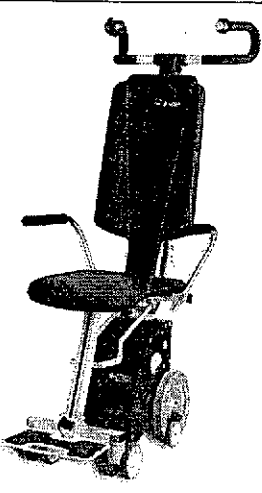
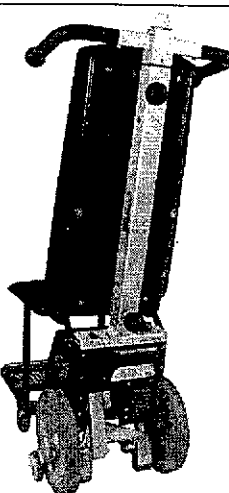
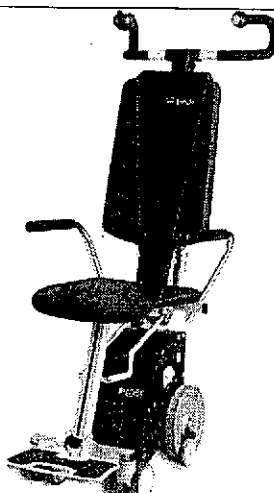
Handle unit

- 1 = control unit
- 2 = handle
- 3 = tightening knob for the handles' horizontal adjustment
- 4 = tightening knob for the handles' height adjustment
- 5 = column
- 6 = tightening knob for the column

Climbing unit

- 7 = upper rod
- 8 = battery pack
- 9 = main wheel
- 10 = climber
- 11 = safety brakes
- 12 = lower rod
- 13 = membrane keypad



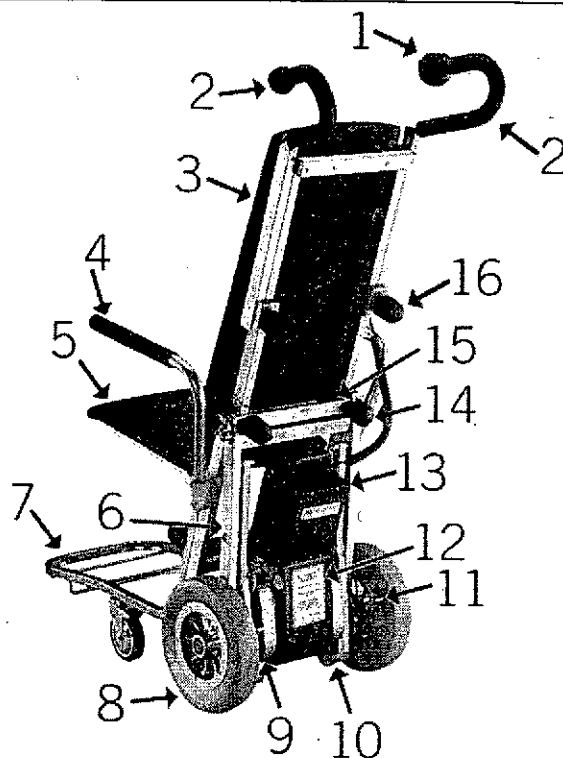
			
s-max (for wheelchair adaption)	s-max sella (with fixed seat)	s-max aviation (with fixed seat)	s-max sella aviation (with fixed seat)

Technical data s-max	s-max	sella	aviation	sella aviation
Height (mm)	1200-1650	1100-1470	1096-1500	1190-1570
width handle / unit (mm)	517/321	517/321	474/379	517/375
depth handle / unit (mm)	230/320	210/320	860/985	210/340
total weight (kg)	20,5	33,5	36	35,5
maximum lifting capacity (kg)	120	135/160	160	160
batteries	2 x 12 V / 3,3 Ah sealed lead acid			
direct current motor	24 V / 178 W (275W)		24 V / 275 W	
climbing speed	app. 300 steps, continually adjustable			
capacity with one battery charge	15 - 30 floors, depending on the load			
maximum height of step	22 cm		25,5 cm	
noise level	the device's A weighted noise level lies typically below 70 dB (A)			
storing/operating temperature, device	0° C up to + 60° C / - 30° C up to + 50° C			
storing/operating temperature, batteries	0° C up to + 60° C / - 30° C up to + 50° C			
vibrations	the weighted RMS value of acceleration the upper body is exposed to lies typically below 2.5 m/s ²			

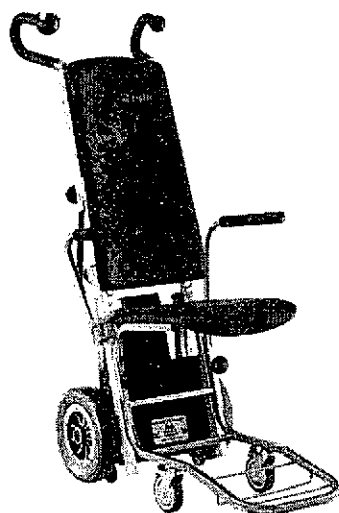
c-max family

2.2 Features of the c-max

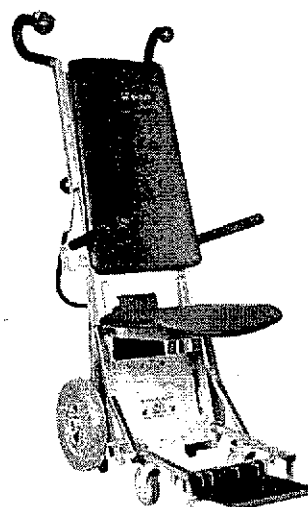
- 1 = control unit
- 2 = handles, adjustable
- 3 = back rest
- 4 = arm rest, swivels out
- 5 = C-part plus seat
- 6 = climbing frame
- 7 = foot rest, folds in
- 8 = main wheel
- 9 = lever with chain drive
- 10 = climber and climbing foot
- 11 = safety brake
- 12 = climbing unit
- 13 = battery pack
- 14 = tightening knobs for the back rest
- 15 = single step switch
- 16 = tightening knob for the handle



c-max u1



c-max u2



Technical data c-max	U1	U2
height	1090 mm	1130 mm
width without arm rests	440 mm	430 mm
width with arm rests attached	485 mm	680 mm
depth with the foot rest folded in	730 mm	670 mm
depth with the foot rest folded out	915 mm	785 mm
total weight	31,7 kg	35,7 kg
maximum lifting capacity	140kg / 160kg	
batteries	2 x 12 V / 5 Ah sealed lead acid	
direct current motor	24 V / 275 W	
climbing speed	8 - 23 steps / minute, continually adjustable	
capacity with one battery charge	app. 300 steps, depending on the load	
maximum height of step	21 cm	
noise level	the device's A weighted noise level lies typically below 70 dB	

	(A)
storing/operating temperature, device	0° C up to + 60° C / - 30° C up to + 50° C
storing/operating temperature, batteries	0° C up to + 60° C / - 30° C up to + 50° C
vibrations	the weighted RMS value of acceleration the upper body is exposed to lies typically below 2.5 m/s ²

1.7 Comparison to legally marketed device (Substantial Equivalence):

The c-max and s-max product families are essentially equivalent in intended use, design and function to the SCALAMOBIL by Ulrich Alber GmbH (K920105).

The Chart below summarizes the similarities and differences:

	c-max	s-max	Scalamobil (K920105)
Stairclimber			
Height	1090 / 1130 mm	1096 - 1650 mm	1150 - 1550 mm
Width	440 - 680 mm	321 - 517 mm	480 mm
Max. Load	140 / 160 kg	120 / 135 / 160 kg	160 kg
Total weight	31,7 / 35, 7 kg	36 kg	24,5 kg
Performance			
steps	app. 300	app. 300	Up to 300
speed	8 - 23 steps / minute continually adjustable	8 - 23 steps / minute continually adjustable	6-16 steps / minute continually adjustable
battery	2x12V, 275 W	2x12V, 178/275W	2x12V, 176 W

Further information on Scalamobil refer to Exhibit #7.

1.8 Biocompatibility Information:

Approval for seat material according to DIN EN ISO 10993-5.

1.9 Labeling:

Exhibit 5 shows the labels that are applied to the device.

1.10 Quality Assurance and Manufacturing Controls:

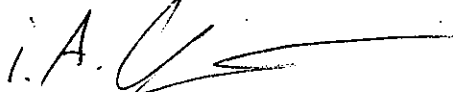
AAT Alber Antriebstechnik GmbH operates to an established and certified quality system based on ISO 9001, and ISO 13485 requirements.

We would appreciate your reviewing this information at your earliest convenience so that a prompt reply to our request for 510(k) clearance can be processed.

If you have any questions, or require additional information, please call me at (409) 995 0741 or email me at s.bankston@beoberlin.de.

Sincerely,

AAT Alber Antriebstechnik GmbH



Stefanie D. Bankston
Official Correspondent for Lifestand

SD



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

AAT Alber Antriebstechnik GmbH
% BEO MedConsulting Berlin GmbH
Mrs. Stefanie D. Bankston
2611 Shark Circle
Texas City, Texas 77591

DEC 30 2010

Re: K103122

Trade/Device Name: c-max, c-max U1, c-max U1 160kg, cmax U2, c-max U2 160kg,
s-max, s-max 160kg, s-max aviation, s-max sella, s-max sella 160kg,
s-max sella aviation

Regulation Number: 21 CFR 890.5150

Regulation Name: Powered patient transport

Regulatory Class: II

Product Code: ILK

Dated: September 13, 2010

Received: October 21, 2010

Dear Mrs. Bankston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

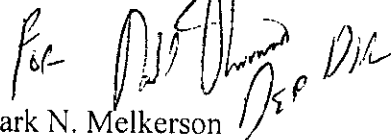
or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 30 2010

Page 1 of 1510(k) Number (if known): K103122**Device Names:**

- c-max, c-max U1, c-max U1 160kg, c-max U2, c-max U2 160kg
- s-max, s-max 160kg, s-max aviation, s-max sella, s-max sella 160kg, s-max sella aviation

Indications For Use:

The products c-max and s-max offer motorized stair-climbing support for disabled seated persons e.g. with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc. to move from one level to another with or without manual wheelchair adaption.

Prescription Use _____
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use X
(21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K103122